REMARKS

Rejection Under 35 U.S.C. § 102

Claims 1-8 and 15-23 were rejected under 35 U.S.C. § 102(b) as being anticipated by International Publication No. WO 99/62580 to Sinderby *et al.* ("Sinderby"). Applicants respectfully traverse the rejection for at least the reasons set forth below.

In general, the present invention relates to a device and method for controlling a positive pressure assist to a patient during expiration. For that purpose, a level of electrical activity of a patient's respiration-related muscle is measured during expiration. Then, in response to the measured level of electrical activity, the positive pressure assist is adjusted so as to minimize the level of electrical activity of the patient's respiration-related muscle during expiration.

Specifically, independent claim 1 is directed to a method of controlling positive pressure assist to a patient during expiration. The method includes measuring the level of electrical activity of a patient's respiration-related muscle during expiration and, in response to the measured level of electrical activity, adjusting a level of positive pressure assist to the patient during expiration in view of minimizing the level of electrical activity of the patient's respiration-related muscle during expiration.

Independent claim 16 is directed to a device for controlling positive pressure assist to a patient during expiration. The device includes means for measuring a level of electrical activity of a patient's respiration-related muscle during expiration and means for, in response to the measured level of electrical activity, adjusting a level of positive pressure assist to the patient during expiration in view of minimizing the level of electrical activity of the patient's respiration-related muscle during expiration.

Independent claim 17 is directed to a device for controlling positive pressure assist to a patient during expiration. The device includes a detector of a level of electrical activity of a patient's respiration-related muscle during expiration and a controller of the level of positive pressure assist to the patient during expiration. The controller is supplied with the measured level of electrical activity and controls the level of positive pressure assist to the patient during

expiration in view of minimizing the level of electrical activity of the patient's respiration-related muscle during expiration.

Applicants respectfully submit that Sinderby does not teach or suggest a method or a device for controlling positive pressure assist to a patient during expiration, as required by Applicants' independent claims 1, 16 and 17. Instead, Sinderby illustrates, in Figure 10 and accompanying description, a neuro-ventilatory efficiency computation device 601 for adjusting the pressure assist to a patient provided by a pressure assist unit 604. A neuro-ventilatory efficiency index is used, this neuro-ventilatory efficiency index expressing the EMGdi signal intensity for a given lung volume or the lung volume for a given EMGdi signal intensity.

Still referring to Sinderby's Figure 10 and accompanying description, the neuro-ventilatory efficiency computation device 601 receives as inputs a given, fixed inspiratory lung volume and a measured EMGdi signal 508. Then, the intensity of the measured EMGdi signal 508 for the given inspiratory lung volume is determined. When the intensity of the measured EMGdi signal for the given inspiratory lung volume and, therefore, the neuro-ventilatory efficiency index have increased by at least a given percentage, the pressure assist from the pressure assist unit 604 is increased by a preset increment until the intensity of the EMGdi signal is restored to a predetermined, preset value. In the same manner, when the intensity of the measured EMGdi signal for the given inspiratory lung volume and, therefore, the neuro-ventilatory efficiency index have decreased by at least a given percentage, the pressure assist from the pressure assist unit is decreased by a preset decrement until the intensity of the EMGdi signal is restored to the predetermined, preset value.

In Figure 11 and accompanying description, Sinderby describes a system for adjusting a level of "extrinsic PEEP" so as to neutralize a level of "intrinsic PEEP" during pre-inspiratory breathing efforts. An EMGdi signal at the onset of inspiratory flow is detected. When the detected EMGdi signal at the onset of inspiratory flow is higher than a given limit/threshold, the level of applied "extrinsic PEEP" is automatically or manually increased. When the detected EMGdi signal at the onset of inspiratory flow is lower than a given limit/threshold, the level of applied "extrinsic PEEP" is automatically or manually decreased.

As can be appreciated from the above summary, Sinderby does not teach control of a positive pressure assist during expiration. For example, page 19, lines 2, 13, 20 and 27 of Sinderby's disclosure describes an inspiratory lung volume. Also, Sinderby at page 18, lines 14-15 discloses that the EMGdi signal intensity is obtained during the 400 ml inspiration starting from en-expiratory lung volume. Finally, page 20, lines 4 and 12-13 of Sinderby clearly describes that the intensity of the signal 508 (EMGdi signal intensity) is measured for the given inspiratory lung volume.

Further, Sinderby, from page 21, line 27 to page 22, lines 1-3, describes that the level of pre-inspiratory effort is obtained through the EMGdi signal intensity during for example a 100 ms period immediately preceding the onset of inspiratory flow. Those of ordinary skill in the art will appreciate that this period falls outside the expiration phase and relates to the beginning of the inspiration phase.

Accordingly it is submitted that Sinderby fails to describe control of a positive pressure assist to a patient during expiration. Sinderby also fails to describe measurement of electrical activity of a patient's respiration-related muscle during expiration.

As can also be appreciated from the above summary, Sinderby further fails to teach or suggest, in order to control a positive pressure assist to a patient during expiration, to minimize the level of electrical activity of the patient's respiration-related muscle during expiration. Instead, Sinderby teaches control of the pressure assist in relation to a predetermined, preset value or a given limit/threshold during inspiration.

Applicants now refer to the comments on page 2 of the Office action highlighting the Sinderby reference at page 7, lines 22-26, and indicating that the cited passage states that the device of Sinderby is applicable with most any respiratory muscle signal (i.e. that includes at least inspiration and expiration).

Applicants respectfully disagree with this broad interpretation of the meaning of the Sinderby passage of page 7, lines 22-26. This passage of Sinderby indicates that although the preferred embodiment of Sinderby's invention will be described in relation to a double

subtracted EMGdi signal, it should be kept in mind that the concept of Sinderby's invention can be used with any respiratory muscle signal. This is intended to mean that the concept of the Sinderby's invention could be used with EMG signals originating from a muscle other than the diaphragm.

As discussed hereinabove, the concept of Sinderby's invention is to control a pressure assist device during the inspiratory phase. Even if Sinderby uses another respiratory muscle signal, i.e. a signal from another respiration-related muscle, the signal will be measured during the inspiration phase to control the pressure assist device during this phase. Applicants do not understand how one could control the pressure assist device during the inspiration phase in accordance with the concept of the invention of Sinderby by measuring an EMG signal during the expiration phase. Moreover, the passage of Sinderby at page 7, lines 22-26 still fails to anticipate the feature that, in order to control a positive pressure assist to a patient during expiration, the level of electrical activity of the patient's respiration-related muscle is minimized during expiration, since the concept of Sinderby's invention is to control the pressure assist in relation to a predetermined, preset value or a given limit/threshold during inspiration.

In view of the above arguments, Applicants respectfully submit that independent claims 1, 16 and 17 are allowable over the teaching of Sinderby. Applicants further submit that claims 2-15 and 18-30, which depend either directly or indirectly upon independent claims 1 and 17, are patentable at least for all of the reasons presented above with respect to independent claims 1, 16 and 17. Accordingly, Applicants submit that claims are in condition for allowance.

Respectfully submitted,

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